

REMARKS

Claims 1-7, 9-11, 14, and 23-34 are pending in the application with claims 1 and 10 amended and new claims 23-34 added herein.

Applicant expresses appreciation for the telephonic interview on March 8, 2010 between James Lake, attorney, and Ann Schillinger, examiner.

Applicant understands agreement was reached that the included amendments to claims 1 and 10 overcome the rejection of such claims over DiMatteo (US Patent No. 7,267,686) under 35 U.S.C. 102(e) as being anticipated.

Applicant requests allowance of such claims in the next Office Action.

Claims 21 and 22 were rejected under 35 U.S.C. 112, first paragraph, as lacking a written description in the specification. Without admitting to the propriety of the rejection, Applicant herein cancels claims 21 and 22. Claim 12 was rejected as being unpatentable over DiMatteo in view of Yang (US Pub. No. 2002/0138138) and is cancelled herein merely as being inconsistent with the closed composition set forth in amended claim 10.

New claims 23-34 are added herein as supported at least by page 5, lines 30-34 of the specification to address the subject matter of previous claim 12. Review of the prior art, including DiMatteo, fails to reveal suggestion of a prosthetic valve including at least one flap "consisting of" a flexible open work structure of a medically acceptable metal coated with a degradable sealing material, as set forth in claims 23 and 32. Page 5 of the Office Action acknowledges that DiMatteo does not disclose a degradable coating "over the valve." Instead, the Office Action relies on Yang as allegedly teaching a coating for "reducing the wear of prosthetic parts." Even

so, neither DiMatteo nor Yang suggest at least one flap “consisting of” a coated, flexible open work structure, as claimed. Both DiMatteo and Yang describe additional components. A combination of references cannot be considered to suggest subject matter that is absent from both references.

Also, paragraph 59 of Yang merely states that “all exposed edges of the stent body 22 are electropolished or coated with a layer of lubricious material (e.g., PTFE or ‘TEFLON’) to eliminate any sharp corners and thus reduce wear on the flexible membranes 24.” Yang does not suggest coating flexible membranes 24. Consequently, Yang may not be considered to suggest coating the claimed at least one flap of the prosthetic valve in claims 23 and 32.

Further, Yang merely describes using a “lubricious material,” which is not necessarily “degradable” within the meaning of claim claims 23 and 32. Such claims state the degradable sealing material is “configured as an initial coating to prevent leakage through the flexible openwork structure until such time as a living subject develops a coating over the at least one flap by endothelialisation.” In contrast, PTFE or “TEFLON” listed in Yang as an example of a “lubricious material” is known for its durability and wear resistance and that is precisely the purpose for which Yang suggests using it, to “reduce wear” on flexible membranes 24. A finding that the lubricious material of Yang describes a degradable sealing material, as claimed, would frustrate the intended purpose of Yang. If the lubricious material degrades, then it cannot eliminate sharp corners and reduce wear on flexible membranes 24 as required by Yang. The Office Action does not provide

substantial evidence that "lubricious material," PTFE, or "TEFLON" may be considered to describe the degradable sealing material as expressly defined in claims 23 and 32.

Still further, the lubricious material of Yang cannot be considered as inherently degradable in a manner that discloses the "degradable sealing material" of claims 23 and 32. "The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency." In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (citations omitted) (emphasis in original); MPEP § 2112 (2007). Further, "[i]n relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added); MPEP § 2112 (2007).

At least for the reasons indicated above, Applicant asserts that claims 23-34 are patentable over the cited combination of references and other references of record.

Applicant herein establishes adequate reasons supporting patentability of claims 1-7, 9-11, 14, and 23-34 and requests allowance of all pending claims in the next Office Action.

Respectfully submitted,

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